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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,574

Applicant(s)

LANDAU, STEVEN M.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the request for extension of time and the Response to Restriction Requirement, both filed 11/24/03 is acknowledged.

Applicant's election *without* traverse of Claims 1-17 in the reply filed on 11/24/03 is acknowledged.

Claims 1-17 are pending. Claims 18-20 are withdrawn from consideration as being directed to non-elected subject matter. Claims 1-17 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (US Pat. No. 5,456,351).

Johnson discloses a method and apparatus for supplying two-part systems that may be required to be separated until just prior to use and discloses methods for taking medication supplied in a dispenser carrying at least two constituent parts. The dispenser comprises a tapered

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cup adapted for containing a second constituent and provided with a substantially flat upper edge or radial flange. The cup is closed by a lid removably secured to the cup's upper edge, the lid comprising two centrally separated layers receiving a first constituent (see reference column 1, lines 15-34); (col. 2, lines 5-14); Abstract and Claims. Johnson discloses that when the dispenser is used in pharmaceuticals, the first constituent (20) may comprise, for example, a solid medication, while the second may comprise a liquid, i.e., water or a second medicine, which is to be taken in conjunction with the first. The first constituent may then either be consumed by the user followed by the consumption of the second constituent, or the two may be combined so as to react to produce an appropriate substance, which is then consumed (col. 5, lines 45-54).

Particular examples of combinations for which the dispenser may be suitably employed includes medications that need to be mixed together, mixed with a liquid or taken with a liquid are also suitable. For example, aspirin and water, contact lens and denture cleaning substances and solutions. The solutions may suitably comprise water with a solid substance contained in the lid portion of the dispenser, for example, wherein the solid is dissolved in water (or any other suitable liquid) for use (col. 6, lines 39-54).

Additionally, Johnson discloses that, when employing the dispenser for delivery of medication, the cup may contain a liquid portion of medicine or water, for example, or when used in delivery of chemicals, may comprise a substance, which needs a catalyst or reactant in order to become active (col. 3, lines 37-41).

Johnson at column 1, lines 27-35, discloses that it is often desirable in pharmaceutical uses to have a portion of medicine separated from a second portion so as to preserve the shelf life of the medicine, when, for example, the medicine begins to break down once the two

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constituents are combined or when the combination begins a chemical reaction that results in slow decay of the resulting active substance.

Fig. 6 demonstrates an embodiment of the invention wherein the second constituent is liquid and the first constituent is a solid. The combined constituents may then be employed for their appropriate use (col. 5, lines 31-39).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Schoo *et al.* (US Pat. No. 6,527,109 B2).

Schoo *et al.* disclose a container cap for mounting on a liquid container with liquid-dissolvable additive, wherein the cap has a liquid-dissolvable disk in it that dissolves in the water when the bottle is shaken or inverted. The cap also has an annular cavity between inner and outer walls in the sidewall of the cap into which the liquid can flow through fluid passageways once the disk is at least partially dissolved. A liquid-dissolvable body is mounted within the chamber between the receiving end and the top end. At least part of the liquid-dissolvable body is in fluid communication with the chamber so that liquid from the liquid container that is poured into the chamber contacts the body and at least partially dissolves the body in the liquid. When

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the cap is mounted on a liquid container, such as by screwing it onto a conventional water bottle, the water in the bottle dissolves the liquid-dissolvable body, which can be any additive such as fluoride, vitamins, flavoring, etc. The water, thereafter containing the additive, can be consumed so as to conveniently gain the benefit of the additive (see reference column 1, lines 12-65) and Abstract.

Schoo *et al.* disclose that there is a liquid-dissolvable body, preferably the annular disk (labeled no. 30), rigidly mounted in the chamber (20) to block the fluid passageways. The disk (30) contains an additive that will eventually be completely dissolved in, and thereby incorporated into a liquid, such as water. The disk (30) can be made of a flavoring, coloring, vitamins, baby formula, water-purifying chemicals, nutrients, fluoride, electrolyte-affecting chemicals, or any other human-consumable additive that dissolves in a human-consumable liquid, such as water, milk, soft drinks, fruit juices, etc. (col. 3, lines 57-67). Preferably, the disk (30) is made entirely of the additive in a solidified form, so that after the disk (30) contacts the liquid and dissolves, there are no remnants of the disk. This complete dissolution of the disk (30) permits use of the invention with medications, with which accurate dosing is essential (col. 3, line 67 – col. 4, line 5).

In another embodiment of the invention, as shown in Fig. 8, a cap (110) has a cavity (118) formed between an inner wall (114) and an outer wall (116). The cavity (118) contains particulate (120) that dissolves in liquid when the liquid enters the cavity (118) through the radial fluid passageways (141-145). This embodiment could be used alone or in combination with a disk of liquid-dissolvable additive material (col. 5, lines 58-65).

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Additionally, Schoo *et al.* disclose that it is known to combine one material with another to dissolve the first in the second and that it is conventionally known to place a liquid in a container and place a second material, whether liquid or particulate, in the lid for that container (col. 1, lines 12-27).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US Pat. No. 5,456,351).

The teachings of Johnson have been delineated above. Johnson teaches a method and apparatus for supplying two-part systems that may be required to be separated until just prior to use and discloses methods for taking medication supplied in a dispenser carrying at least two

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constituent parts. The dispenser comprises a two-part lid of paper-foil or paper-plastic material (col. 2, lines 22-30). The dispenser comprises a two-part lid comprising a first constituent (i.e., solid) separated from the second constituent (i.e., liquid). Johnson does not teach a cap assembly.

However, it is the position of the Examiner that there is no criticality observed between the cap assembly instantly claimed and the two-part lid taught by Johnson since the two-part lid of Johnson is functionally equivalent in structure to the cap assembly instantly claimed because the two-part lid functions to separate the first and second constituents from each other until just prior to use and similarly, the cap assembly instantly claimed also serves to contain the flow of fluid out of the fluid container and separate the liquid from the solid constituents. The prior art teaches a dispenser used in pharmaceutical applications for delivering medication whereby the first constituent is in solid form and separated from the second constituent, which is in liquid form, to assist in consumption of the first constituent solid medication (see claims). Hence, the instant invention is rendered *prima facie* obvious over the prior art of record.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays from 8:00 A.M. to 4:30 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

H. N. Sheikh *HNS*.

Patent Examiner

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August 16, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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